PSJ3

Exhibit 340

GAO Meeting on DEA (Confidential, not for external circulation)
Potential Talking Points

Outline:

A. Intro to meeting participants
B. Background on HDMA,
C. Give bkgnd of key DEA regulations of wholesale distributors
D. Recent concerns
    a. suspicious orders monitoring,
    b. interpretations of the CSA and implementing regulations, and
    c. registration revocations.
E. Key messages

1. Intro to meeting participants

Anita Ducca, Scott Melville, David Durkin, others?

2. Background on HDMA:

Who we represent, show the graphic of wholesale distribution we have on line, number of members, etc.

3. Bkgnd on key DEA regulations of wholesale distributors (details spelled out in Attachment 1)

- Registration with DEA
- Security
- Reporting
- Suspicious orders identification and monitoring
- Preventing diversion

4. Recent concerns

HDMA has taken pains to develop an interactive relationship with DEA since the 1990's. Apparently, 10 or more years ago it was "rocky". Since the early 2000's, it seemed to take a turn for the better, and we've been working since then to maintain a good relationship. Recently, DEA has exerted extreme pressure on wholesale distributors to take controlled substances suspicious order responsibilities much further.

- DEA "invited" members of the distribution industry, firm by firm, to a meeting where DEA point blank told them that they should identify customers who are selling for illicit purposes, e.g. "pill mills" or illicit Internet pharmacies such as those filling orders without a prescription.
- This was followed by revoking several registrations (2007)

HDMA went to great lengths to seek resolutions with DEA.

- Many meetings to seek a better understanding of their expectations (see attached chronology)
- Prepared a comprehensive guideline on suspicious order monitoring/reporting for wholesalers (ICG)
- Received a letter from DEA commending the effort
- Webinar and other communications with our members
- HDMA's members have put extensive monitoring systems in place
- HDMA's members have stopped sales to some customers altogether

DESPITE THESE EFFORTS, DEA HAS REVOKED ANOTHER WHOLESALE DISTRIBUTOR REGISTRAITON (Spring, 2010)

Additional issues:

- We believe there is an actual change in the regulations that they made through enforcement actions, not notice and comment

- DEA's guidance on identifying "suspicious orders" has been vague or even outright unattainable by a wholesale distributor (e.g., "suspicious order" volumes set unrealistically low; due to confidentiality, expertise, and resource demands, inability we can't always identify legitimate

We held a number of meetings with DEA, and attempted to reach an understanding of their expectations (see attached chronology of events).

DEA has also stated:

DEA's guidance is vague and shifts over time and little,
Wholesale distributors supply DEA with a wealth of information/data on sales and shipments.

if any, further analysis from DEA is made available, despite a wealth of information being sent to DEA. Currently

are not backed by DEA support has given wholesale distributors general "criteria" for when the customer might be selling to those intending inappropriate use, but it is more complex than that. DEA's criteria are often subjective e.g., if the pharmacy places large orders of controlled substances but orders very few other drugs.[1]
Distributors have taken measures to evaluate customers, track ordering, and stop sales when appropriate. However, DEA's extreme expectations coupled with very vague guidelines place wholesale distributors in an untenable position.

A. suspicious orders monitoring,

- The DEA registration cannot be used to determine who is legitimate.
- DEA cannot tell wholesale distributors who they may sell/ship to.
- In contrast to what has been the interpretation of DEA's regulations for monitoring and reporting of "suspicious orders" and for "preventing diversion" these meetings seemed to be giving a change in interpretation without notice and comment. Essentially, that wholesale distributors are not only responsible for preventing diversion from their own facilities, but for diversion by those to whom they sell.

    a. interpretations of the CSA and implementing regulations, and
    b. registration revocations.

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[1] Examples of Criteria from the Chemical Handler's Manual, include: Customers who don't seem to know industry practice or who fail to provide reasons for an order at variance with accepted legitimate industry practice, Customer who provides evasive responses to any questions or is unable to supply information as to whether chemicals are for domestic use or for export, and Pharmacies that stock large shelf volumes in stores that have repeated thefts or other sales problems.

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Distributors have taken measures to evaluate customers, track ordering, and stop sales when appropriate. However, DEA's extreme expectations coupled with very vague guidelines place wholesale distributors in an untenable position.

DEA believes that wholesalers can readily identify excessive orders, but it is not that simple. - called "internet Pharmacies" is that it involves a pharmacy that may be filling prescriptions that have been issued outside the course of legitimate medical practice, that is, there is not a doctor-patient relationship. So the wholesalers are twice removed from the potential unlawful activity but are being put in the position to try and police this activity.

Key concerns:

- **It is unreasonable for DEA to expect a distributor to seek information about pharmacies that they are barred from, either through confidential business practices or legal restrictions (e.g. HIPAA).**
  - **DEA has asked distributors where pharmacy's prescriptions came from; also to research the pharmacy's customer base.**
- **Even if the distributor does their due diligence regarding a customer, there is no guarantee that that the pharmacy will tell the truth. (A specific problem encountered by one of our members.)**
- DEA used an extreme tactic by suspending a license. This action is intended for when there is an "imminent threat to the public health and safety".
- DEA has taken action against rogue pharmacies but it has been slow. Some of the actions DEA has taken against distributors involve **pharmacies that are still registered under state and federal law.**
- **DEA's criteria for when to take additional action are <u>very</u> subjective.**
- **Although DEA uses volume as a criteria, they don't provide specific numbers.** Even if they did,
  - How far over the cutoff should the order be before the distributor is supposed to take action or stop the sale?

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* How can a new, larger order be used to determine an unusual selling pattern when business models are highly variable and change rapidly?

Additional problems include:

- Distributors are not in the pharmacy business. Yet they are expected to evaluate their customers with little expertise in pharmacy selling patterns, marketing, etc.
- DEA's pharmacy registration practice includes little if any, oversight. Although we understand that DEA has recently stepped up its pharmacy oversight, prior to now, it has been very limited.
- The Internet has made the concept of suspicious ordering, as it was designed 30 years ago, very outdated. Similarly for medical practice. For example, how should any criteria fit in with the use of pain clinics where prescriptions may intentionally focus on a limited number of controlled substances by design, or physicians who may only review a medical record without ever seeing a patient before issuing a prescription?

In 2006, based on concerns about sales of drugs by wholesale distributors' customers to internet pharmacies, DEA appeared, to us, to be changing their expectations. Whereas in the past suspicious orderrequirements, with

Attachment 1

Key DEA Regulations pertaining to wholesale distributors

DEA regulates and tracks all Schedule II controlled substance distribution from the point of manufacture to the location where the controlled substance ultimately will be dispensed to the consumer.

The regulations in Title 21, Code of Federal Regulations (C.F.R.) part 1300 to 1316 apply to all individuals and firms desiring to conduct business in CS. All such individuals and firms must

- be registered with DEA
- are required to maintain complete and accurate inventories and records of all transactions involving CS
- maintain security for storage of controlled substances
- Sections 823(b) and (d) of the CSA call for the maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels

In addition, distributors are required by 21 C.F.R. § 1301.74(b) to [identify] and report suspicious orders of CS:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. [Emphasis added.]

Further, only authorized, DEA-registered entities such as pharmacies and physicians may order controlled substances of any kind.

- All orders of Schedule II controlled substances placed in the United States – including all opioids being considered for the REMS – must be documented on the specially designed three-part DEA Form 222 (commonly referred to as "Form 222").
- A copy of every completed Form 222 is filed with DEA.
- An order for a Schedule II controlled substance:
  - cannot be filled by the distributor until it receives a properly executed Form 222 from a DEA-registered pharmacy or other provider.
  - cannot be shipped to any customer unless the customer is also a DEA registrant.
- The requirements for ordering Schedule II drugs via a Form 222 extend to distributors ordering products from the original manufacturer.

Distributors make three other important reports to the DEA.

- **ARCOS**-- distributors must report, on at least a quarterly basis, their inventories, acquisitions, and dispositions of all substances in Schedules I and II, as well as all narcotic and Gamma-Hydroxybutyric Acid (GHB) substances in Schedule III.[3]
- **Suspicious Orders reporting –** Wholesale distributors must report to DEA if they detect that a customer's controlled substances volume or pattern of ordering might constitute a "suspicious order."[4]

[3] 21 C.F.R. § 1304.33 (Reports to ARCOS (Automation of Reports and Consolidated Orders System)).

[4] 21 C.F.R. § 1301.74(b) (Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs).

- **Losses or thefts** -- Distributors must report all losses or thefts of controlled substances on DEA Form 106 and include all details such as the identity and amount of the controlled substance that was lost or stolen.5

[5] 21 C.F.R. § 1301.74(c) (Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs)